Complete Summary

GUIDELINE TITLE

Mastalgia.

BIBLIOGRAPHIC SOURCE(S)

Rosolowich V, Saettler E, Szuck B, Lea RH, Levesque P, Weisberg F, Graham J, McLeod L, Rosolowich V, Society of Obstetricians and Gynecologists of Canada (SOGC). Mastalgia. J Obstet Gynaecol Can 2006 Jan;28(1):49-57. [84 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Mastalgia (cyclical and non-cyclical breast pain)

GUIDELINE CATEGORY

Counseling Management Treatment

DISCLAIMER

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

Oncology Psychiatry Psychology

INTENDED USERS

Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To review the current management of women with breast pain

TARGET POPULATION

Women with mastalgia (cyclical and non-cyclical breast pain)

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Patient education and reassurance
- 2. Use of a well-fitting support bra
- 3. Discontinuation or changes in dose, formation, or scheduling of hormone replacement therapy (HRT)
- 4. Flaxseed
- 5. Non-steroidal anti-inflammatory gel, such as diclofenac 2% in pluronic lethicin organogel (PLO)
- 6. Tamoxifen
- 7. Danazol

Note: The following interventions were discussed but not recommended: reduction in caffeine intake, vitamin E, evening primrose oil, mastectomy or partial mastectomy.

The following interventions were discussed, but no recommendation for or against was made: use of oral contraceptives, vitamin B6, low-fat diet, isoflavones, herbs such as ginseng and chasteberry, progesterone cream, and bromocriptine.

MAJOR OUTCOMES CONSIDERED

- Effective and timely management of women with breast pain
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search was performed to identify reports published in English between 1975 and July 2003 using MEDLINE and Cochrane Database of Systematic Reviews.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence*

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence from well-designed controlled trials without randomization.
- **II-2**: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.
- **II-3**: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
- *Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on the Periodic Health Exam.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations*

- A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination.
- D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.
- E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Comparison has been made with management protocols in the literature, but no clinical guidelines have been located. No formal clinical testing has taken place.

This guideline has been reviewed by the Breast Disease Committee and approved by the Executive and Council of the Society of Obstetricians and Gynecologists of Canada. This guideline has also been developed in collaboration with the Breast Health Centre, Winnipeg Regional Health Authority.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The level of evidence (I-III) and classification of recommendations (A-E) are defined at the end of the "Major Recommendations" field.

Mastalgia and Breast Cancer

Psychological Factors

^{*}Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on the Periodic Health Exam.

1. Education and reassurance is an integral part of the management of mastalgia and should be the first-line treatment. (II-1 A)

Well-Fitting Support Bra

2. The use of a well-fitting bra that provides good support should be considered for the relief of cyclical and noncyclical mastalgia. (II-3 B)

Hormones

Hormone Replacement Therapy (HRT)

3. A change in dose, formulation, or scheduling should be considered for women on HRT. HRT may be discontinued if appropriate. (III C)

Caffeine

4. Women with breast pain should not be advised to reduce caffeine intake. (1 E)

Vitamins

Vitamin E

5. Vitamin E should not be considered for the treatment of mastalgia. (1 E)

Fat

Evening Primrose Oil (EPO)

6. There is presently insufficient evidence to recommend the use of EPO in the treatment of breast pain. (II-2 C)

Phytoestrogens

Flaxseed

7. Flaxseed should be considered as a first-line treatment for cyclical mastalgia. (I A)

Medications

Topical Non-Steroidal Anti-inflammatory Drugs

8. Topical, non-steroidal anti-inflammatory gel, such as diclofenac 2% in pluronic lethicin organogel (PLO), should be considered for pain control for localized treatment of mastalgia. (I A)

Tamoxifen and Danazol

9. Tamoxifen 10 mg daily or danazol 200 mg daily should be considered when first-line treatments are ineffective. (I A)

Mastectomy

10. Mastectomy or partial mastectomy should not be considered an effective treatment for mastalgia. (III E)

Definitions:

Level of Evidence*

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence from well-designed controlled trials without randomization.
- **II-2**: Evidence from well-designed cohort (prospective or retrospective) or case-control analytic studies, preferably from more than one centre or research group.
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Classification of Recommendations**

- A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination.
- D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.
- E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

CLINICAL ALGORITHM(S)

None provided

^{*}The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on the Periodic Health Exam.

^{**}Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on the Periodic Health Exam.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Utilizing the information will increase knowledge, enabling a consistent approach, which will reduce the number of ineffective interventions and ensure appropriate use of medications.

POTENTIAL HARMS

- Side effects of tamoxifen commonly observed in short-term treatment for mastalgia include hot flashes (10%), menstrual irregularity/amenorrhea (10%), weight gain, nausea, vaginal dryness, and bloating (5% or less). Thromboembolic events, endometrial cancer, and cataracts are rare but serious side effects of tamoxifen; their incidence in short-term, low-dose treatment regimens for mastalgia is not known.
- Side effects of danazol at the 200 mg dose include weight gain (30%), menstrual irregularity/amenorrhea or menorrhagia (50%), deepening of the voice (10%), and hot flashes (10%).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline reflects emerging clinical and scientific advances as of the date issued and are subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Jan

GUIDELINE DEVELOPER(S)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Obstetricians and Gynaecologists of Canada

GUIDELINE COMMITTEE

Breast Disease Committee of the Society of Obstetricians and Gynaecologists of Canada

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Society</u> of <u>Obstetricians and Gynaecologists of Canada Web site</u>.

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 4, 2009. The information was verified by the guideline developer on March 4, 2009.

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